K120384

Section 5 – 510(k) Summary

SEP 12 2012

Date Prepared:	21 August 2012
Submitted Name: **Submitter Address:**	Becton, Dickinson and Company 1 Becton Drive Franklin Lakes, NJ 07417 USA
Submitter Telephone No:	201 847 5473
Name of Device:	PhaSeal Closed System Drug Transfer Device
Predicate Device(s):	PhaSeal Protector: K972527, K001368, K090634 PhaSeal Injector: K972527, K980381, K001368, K023747, K060866, K092782, K110023 PhaSeal Connector: K972527, K001368, K092782
Description of Device:	The PhaSeal® System is a sterile single-use closed system drug transfer device. The closed transfer of liquid takes place through a double membrane technique utilizing self-sealing elastomeric membranes, tightly fitted together through a bayonet fitting on all PhaSeal components. A single lumen cannula perforates the double membranes for the transfer of liquid. When the cannula is retracted the membranes seal off and transfer of environmental contaminants into the system and/or escape of drug or vapor concentrations outside the system, thereby minimizing individual and environmental exposure to drug vapor, aerosols and spills. The PhaSeal® Protector also prevents microbial ingress.
Indications for Use:	The PhaSeal system is a closed system drug transfer device (CSTD) that mechanically prohibits the transfer of environmental contaminants into the system and the escape of drug or vapor concentrations outside the system, thereby minimizing individual and environmental exposure to drug vapor, aerosols and spills. The PhaSeal Protector also prevents microbial ingress.
Technological Characteristics of New Device vs. Predicate Device	The technological characteristics of the subject device are IDENTICAL to those of the predicate device(s)
Summary of Non-Clinical Test Submitted to Determine Substantial Equivalence:	Two peer-reviewed publications - see Appendix II - are submitted to support the amended Indications for Use Statement. As well as Mircobial Ingress testing on the interface between the drug vial and PhaSeal Protector.

1. "Utility of the PhaSeal Closed System Drug Transfer Device," Derek M. McMichael, PharmD; Dawn Moore Jefferson, PharmD; E. Thomas Carey, Pharm D; Ryan A. Forrey, PharmD, MS; Susan M. Spivey, PharmD, DDS; John M. Mulvaney, MHA; James A. Jorgenson, RPh, MS; and R. Douglas Haughs, BS, *Am J Pharm Benefits,* 2011; 3(1): 9-16).
2. "Second Look Utilization of a Closed-System Transfer Device (PhaSeal)," E.Thomas Carey, Pharm D; Ryan A. Forrey, PharmD, MS; Douglas Haughs, BS; Dawn Moore Jefferson, PharmD; James A. Jorgenson, RPh, MS; Derek M. McMichael, PharmD; John M. Mulvaney, MHA; Susan M. Spivey, PharmD, DDS, *Am J Pharm Benefits,* 2011; 3(6): 11-18).

The objective of the first study, entitled "Utility of the PhaSeal Closed System Drug Transfer Device," was to assess the ability of the PhaSeal closed system drug transfer device to prevent contamination of parenteral drug products. The PhaSeal closed system drug transfer device was applied to vials containing sterile culture media. The vials were entered using the PhaSeal system and samples were removed at 24, 48, 72, 96 and 168 hours. Samples were tested by an independent microbiology laboratory for evidence of contamination. A total of 1328 syringes were produced at 4 different institutions. Visual, microscopic, and microbiologic subculture analyses were performed. A failure rate of 1.8% was observed, and supported the alternate hypothesis at the 99% confidence level that the PhaSeal system is capable of maintaining sterility in a controlled environment. Secondary analysis of the data was conducted based on time to failure. The analysis indicated that at the 16-hour mark there is a 98.2% probability that the vials will not be contaminated. Results of this study show that the PhaSeal closed system drug transfer device provides a mechanical barrier to the entry of contaminants into sterile solutions. The study also demonstrates that solutions are expected to remain sterile for up to 168 hours.

The objective of the second study, entitled "Second Look at the Utilization of Closed-System Transfer Devices (PhaSeal)," was to confirm and refine the results and conclusions of the first study. Aliquots of sterile culture medium were transferred from test vials of sterile culture medium to intravenous bags of sterile medium over a 7-day

time period utilizing the PhaSeal Closed System Transfer Device. The IV bag test samples were then held under controlled incubation for 14 days and monitored for evidence of contamination by an independent microbiology laboratory. The results indicate that at the 168-hour mark, the probability of failure was 0.3%. In other words, at 168 hours, the probability that the vial would remain sterile is 99.7%. Although the use of Closed System Transfer Devices has traditionally focused on reducing exposure of healthcare workers to hazardous substances, this study further demonstrates the ability of the PhaSeal System to maintain the sterility of drug vial contents.

Finally, Microbial Ingress testing on the interface between the drug vial and protector was performed in accordance with "Guidance for Industry and FDA Staff - Intravascular Administration Sets Premarket Notification Submissions [510(k)]". Based on the results of the study, microbial ingress was NOT observed on any of the samples with the PhaSeal Protector. These results demonstrate the subject device's self-sealing elastomeric membranes are in fact capable of preventing the transfer of microbes from outside to the inside of the sterile drug solutions.

Summary of Non-Clinical Test Submitted to Determine Substantial Equivalence

Clinical studies are not submitted to support substantial equivalence.

Conclusions Drawn from Non-Clinical Tests

Conclusions drawn from publication entitled "Utility of the PhaSeal Closed System Drug Transfer Device": The analysis indicated that at the 168-hout mark there is a 98.2% probability that the vials will not be contaminated. Results of this study show that the PhaSeal closed system drug transfer device provides a mechanical barrier to the entry of contaminants into sterile solutions. The study also demonstrates that solutions are expected to remain sterile for up to 168 hours.

Conclusions drawn from the publication entitled "Second Look at the Utilization of Closed-System Transfer Devices (PhaSeal)": The results indicate that at the 168-hour mark, the probability of failure was 0.3%. In other words, at 168 hours, the probability that the vial would remain sterile is 99.7%. Although the use of Closed System Transfer Devices has traditionally focused on reducing exposure of

healthcare workers to hazardous substances, this study further demonstrates the ability of the PhaSeal System to maintain the sterility of drug vial contents.

Conclusions drawn from Microbial Ingress studies performed in accordance with "Guidance for Industry and FDA Staff - Intravascular Administration Sets Premarket Notification Submissions [510(k)]": Based on the results of the study, microbial ingress was NOT observed on any of the samples with the PhaSeal Protector. These results demonstrate the subject device's self-sealing elastomeric membranes are in fact capable of preventing the transfer of microbes from outside to the inside of the sterile drug solutions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 12 2012

Mr. John Roberts
Regulatory Affairs Specialist
Becton, Dickinson and Company - Medical Surgical Systems
1 Becton Drive
Franklin Lakes, New Jersey 07417

Re: K120384
Trade/Device Name: PhaSeal® - A Closed System Transfer Device
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: LHI
Dated: August 23, 2012
Received: August 24, 2012

Dear Mr. Roberts:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use Statement

510(k) Number (if known): _____

Device Name: PhaSeal® – A Closed System Transfer Device

Indications for Use:

The PhaSeal system is a closed system drug transfer device (CSTD) that mechanically prohibits the transfer of environmental contaminants into the system and the escape of drug or vapor concentrations outside the system, thereby minimizing individual and environmental exposure to drug vapor, aerosols and spills. The PhaSeal Protector also prevents microbial ingress.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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